US ERA ARCHIVE DOCUMENT

DATA EVALUATION RECORD § 72-1(A) -- ACUTE LC₅₀ TEST WITH A WARMWATER FISH

1. CHEMICAL: Cloquintocet-mexyl

PC Code No.: 999999

2. TEST MATERIAL: CGA-185072

Purity: 91.6%

3. CITATION

Authors: H. Rufli, F. Lanter, and A. de morsier

Title: Acute Toxicity Test of CGA-185072 technical to Bluegill

(Lepomis macrochirus)

Study Completion Date:

June 29, 1988

Laboratory:

Ciba-Geigy, Ltd.

Ecotoxicology Department

Basle, Switzerland

Sponsor:

Novartis Crop Protection, Inc.

P.O. Box 18300

Greensboro, NC 27419

Laboratory Report ID:

871686

MRID No.:

443874-10

DP Barcode:

D240854

4. REVIEWED BY: Stephen Carey, Biologist, ERBIII, EFED

Signature:

5. APPROVED BY: Harry Craven, ERBIII, EFED

Signature:

Date: 11/5/99

Date: 11/5/99

6. STUDY PARAMETERS

Scientific Name of Test Organism:

Lepomis macrochirus

Age or Size of Test Organism:

Average of 45 mm

Definitive Test Duration:

Henry To Craven

96 hours

Study Method:

Static

Type of Concentrations:

Measured

7. **CONCLUSIONS**: The study is scientific sound but does not fulfill the guideline requirements.

Results Synopsis:

96-hr LC₅₀: >38 ppm ai

95% C.I.: N/A

Probit Slope: N/A

NOEC: 12.4 ppm ai



8. ADEQUACY OF THE STUDY

A. Classification: Supplemental

B. Rationale: The test containers were gently aerated with the use of dechlorinated tap water as dilution water. Prior to chemical analysis, centrifugation was not conducted even though a precipitate was formed in the test vessels.

C. Repairability: No

9. GUIDELINE DEVIATIONS

- 1. All test containers were gently aerated throughout the study.
- 2. After 30 minutes of exposure, a small deposit of precipitation formed.
- 3. The solvent, alkylphenol-polyglykol-ether, is not from one of EFED's solvent recommendations for study purposes. However, the test organisms in the solvent control level survived, not affecting the category of the study.
- 4. pH of the study at 8.2 8.5 exceeded the recommended range 7.2 7.6.
- 5. Hardness at 184 mg/L CaCO₃ exceeded the recommended range of 40 48 ppm.
- 6. Dechlorinated tap water was used as dilution water
- 7. Test concentrations at 96-hours were not maintained >70% of 0-hour concentrations

10. SUBMISSION PURPOSE:

11. MATERIALS AND METHODS

A. Test Organisms

Guideline Criteria	Reported Information
Species Preferred species is the bluegill sunfish (Lepomis macrochirus)	Lepomis macrochirus
Mean Weight 0.5-5 g	Mean: 1.27 g Range: 1.00 - 1.44 g

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Guideline Criteria	Reported Information			
Mean Standard Length Longest not > 2x shortest	Mean: 45 mm Range: 40-47 mm			
<u>Supplier</u>	Osage Catfisheries Box 222, Missouri, 65065			
All fish from same source?	Yes			
All fish from the same year class?	Yes			

B. Source/Acclimation

Guideline Criteria	Reported Information			
Acclimation Period Minimum 14 days	82 days			
Wild caught organisms were quarantined for 7 days?	N/A			
Were there signs of disease or injury?	No			
If treated for disease, was there no sign of the disease remaining during the 48 hours prior to testing?	N/A			
Feeding No feeding during the study	Last fed 24 hours prior to test initiation			
Pretest Mortality No more than 3% mortality 48 hours prior to testing	<3 % mortality prior to testing.			

C. Test System

Guideline Criteria	Reported Information
Source of dilution water	Carbon filtered dechlorinated tap water
Soft reconstituted water or water from a	
natural source, not dechlorinated tap water	

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Guideline Criteria	Reported Information			
Does water support test animals without observable signs of stress?	Yes			
Water Temperature 17°C or 22°C	23 ± 1°C			
pH Prefer 7.2 to 7.6	8.2 - 8.5 pH			
Dissolved Oxygen Static: ≥ 60% during 1 st 48 hrs and ≥ 40% during 2 nd 48 hrs, flow-through: ≥ 60%	Aeration was used throughout study, Oxygen was generally greater than 84 %.			
Total Hardness Prefer 40 to 48 mg/L as CaCO ₃	184 mg/L as CaCO ₃			
Test Aquaria 1. Material: Glass or stainless steel 2. Size: Volume of 19 L (5 gal) or 30 x 60 x 30 cm 3. Fill volume: 15-30 L of solution	Glass 20 L 15 L			
Type of Dilution System Must provide reproducible supply of toxicant	Static			
Flow Rate Consistent flow rate of 5-10 vol/24 hours, meter systems calibrated before study and checked twice daily during test period	N/A			
Biomass Loading Rate Static: ≤ 0.8 g/L at ≤ 17°C, ≤ 0.5 g/L at > 17°C; flow-through: ≤ 1 g/L/day	0.42 g/L			
Photoperiod 16 hours light, 8 hours dark	16 hrs light, 8 hrs dark			
Solvents Not to exceed 0.5 ml/L for static tests or 0.1 ml/L for flow-through tests	Solvent: 4 mg alkylphenol-polyglykol-ether per liter (.0038 ml/L)			

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D. Test Design

Guideline Criteria	Reported Information				
Range Finding Test If LC ₅₀ >100 mg/L with 30 fish, then no definitive test is required.	N/A				
Nominal Concentrations of Definitive Test Control & 5 treatment levels; dosage should be 60% of the next highest concentration; concentrations should be in a geometric series	Control level, solvent level and 5.8, 10, 18, 32, 58, 100 mg ai/L				
Number of Test Organisms Minimum 10/level, may be divided among containers	10 fish per treatment level or control, 10 per replicate.				
Test organisms randomly or impartially assigned to test vessels?	Yes				
Biological observations made every 24 hours?	Yes				
Water Parameter Measurements 1. Temperature Measured constantly or, if water baths are used, every 6 hrs, may not vary > 1°C 2. DO and pH Measured at beginning of test and ever 48 h in the high, medium, and low doses and in the control	Temperature, Oxygen, and pH were measured daily in each test chamber. Temperature was continuously monitored in the test tanks using min/max thermometers.				
Chemical Analysis Needed if solutions were aerated, if chemical was volatile, insoluble, or known to absorb, if precipitate formed, if containers were not steel or glass, or if flow-through system was used	Samples collected from each test vessel at day 0 and day 4 were analyzed by HPLC. Samples were not filtered or centrifuged before the analyses.				

12. REPORTED RESULTS

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A. General Results

Guideline Criteria	Reported Information				
Quality assurance and GLP compliance statements were included in the report?	Yes				
Recovery of Chemical Percent of nominal: Analytical capability: Limit of quantitation (LOQ):	19-54 % 101-109 % Not reported				
Control Mortality Not more than 10% control organisms may die or show abnormal behavior.	0% morality in the control group.				
Raw data included?	Yes				
Signs of toxicity (if any) were described?	No				

Mortality

Concentration (ppm)			Cumulative Number Dead					
Nominal	Initial Measured	96 hr Measured	Mean Measured	Number of Fish	mber of Hour of Study			7
		Y			24	48	72	96
Control	N/A	N/A	N/A	10	0	0	0	0
Solvent Control	N/A	N/A	N/A	10	0	0	0	0
5.8	n.d.	n.d.	n.d.	10	0	0	0	0
10	4.33	1.93	3.13	10	0	0	0	0
18	9.73	5.03	7.38	10	0	0	0	0
32	17.0	7.87	12.44	10	0	0	0	0
58	29.3	17.3	23.3	10	0	2	2	2
100	51.3	24.7	38	10	3	3	3	3

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Other Significant Results: A slight deposit was observed in concentration 10-100 mg/l (nominal) after approximate 30 minutes of exposure. Unable to calculate a statistically sound C.I. due to low morality values.

B. Statistical Results

Method: not reported

96-hr LC₅₀: >51 ppm ai

95% C.I.: N/A

Probit Slope: N/A

NOEC: N/A

13. VERIFICATION OF STATISTICAL RESULTS

Method: visual observation

96-hr LC₅₀: >38 ppm ai

95% C.I.: N/A

Probit Slope: N/A

NOEC: 12.4 ppm ai

14. REVIEWER'S COMMENTS: Based on the report, the study is scientifically sound but does not fulfill the section 158 requirements. The study partially conforms to the procedures of the subdivision guideline requirements for an acute toxicity test using bluegill sunfish. Based on measured concentrations, the 96-hour EC50 and NOEC exposed to CGA-185072 were >38 and 12.4 ppm ai respectively.

It is important to note that the first three guideline deviations of the experiment-the test concentrations at 96-hours were not >70 % of initial concentration, test containers were aerated throughout the static study, and a small deposit of precipitation was formed in the container-are all mitigated because all concentrations were measured at 0 and 96 hours. The solvent, alkylphenol-polyglykol-ether, is acceptable states since no morality occurred in the solvent control. Additional deviations stated that dechlorinated water was used with a pH of 8.2-8.5 and water hardness of 184 mg/L as CaCO₃ did not meet the recommended guideline requirements. This study is classified as **supplemental** because a definitive chemical analysis was not determined by centrifuging the test material.